

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 20340/S3

APPROVAL LETTER



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NOV 15 1996

NDA 19-322/S-015

NDA 19-323/S-016

NDA 19-966/S-005

NDA 20-337/S-001

NDA 20-340/S-003

Glaxo Wellcome Inc.

Attention: J. Chris Prue, R.Ph.

Director, Dermatology Regulatory Affairs

Five Moore Drive

Research Triangle Park, North Carolina 27709

Dear Mr. Prue:

Please refer to your July 12, 1996 supplemental new drug applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for:

NDA 19-322/S-015 Temovate (clobetasol propionate) Cream, 0.05%;

NDA 19-323/S-016 Temovate (clobetasol propionate) Ointment, 0.05%;

NDA 19-966/S-005 Temovate (clobetasol propionate) Scalp Application, 0.05%;

NDA 20-337/S-001 Temovate (clobetasol propionate) Gel, 0.05%;

NDA 20-340/S-003 Temovate (clobetasol propionate) Emollient, 0.05%.

These supplemental applications provide for a change in the location of the
the manufacture of

stages of

The supplemental applications also provide for the following changes:

*Minor process changes associated with process optimization;

*Deletion of the

We have completed the review of these supplemental applications and they are approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

NDA 19-322/S-015

NDA 19-323/S-016

NDA 19-966/S-005

NDA 20-337/S-001

NDA 20-340/S-003

Page 2

If you have any questions, please contact:

Mary Jean Kozma-Fornaro, R.N., M.S.A.
Consumer Safety Officer
(301) 827-2020

Sincerely yours,



Wilson H. DeCamp, Ph.D.
Chemistry Team Leader, DNDC III
Division of Dermatologic and Dental Drug
Products (HFD-540)
Office of Drug Evaluation V
Center for Drug Evaluation and Research

cc:

Original NDAs 19-322, 19-323, 19-966, 20-337, 20-340

HFD-540/Div. Files

HFD-540/CSO/MJKozma-Fornaro

HFD-540/MO/Walker

HFD-540/Pharm/Alam

HFD-540/Chem/Pappas

HFD-540/TmLdr/DeCamp

HFD-830/E.Sheinin (only for chemistry supplements)

HFD-80

DISTRICT OFFICE

HFD-232

APPROVAL